§ 1310.15 Exempt drug products containing ephedrine and therapeutically significant quantities of another active medicinal ingredient.

(a) The drug products containing ephedrine and therapeutically significant quantities of another active medicinal ingredient listed in paragraph (e) of this section have been exempted by the Administrator from application of sections 302, 303, 310, 1007, and 1008 of the Act (21 U.S.C. 822–3, 830, and 957–8) to the extent described in paragraphs (b), (c), and (d) of this section.

(b) No exemption granted pursuant to 1310.14 affects the criminal liability for illegal possession or distribution of listed chemicals contained in the exempt drug product.

(c) Changes in drug product compositions: Any change in the quantitative or qualitative composition of an exempt drug product listed in paragraph (d) requires a new application for exemption.

(d) In addition to the drug products listed in the compendium set forth in § 1310.01(f)(1)(iv)(A), the following drug products, in the form and quantity listed in the application submitted (indicated as the ''date'') are designated as exempt drug products for the purposes set forth in this section:

EXEMPT DRUG PRODUCTS CONTAINING EPHEDRINE AND THERAPEUTICALLY SIGNIFICANT QUANTITIES OF ANOTHER ACTIVE MEDICINAL INGREDIENT

Supplier	Product name	Form	Date
[Reserved]	.....	.....	

[60 FR 32463, June 22, 1995]

PART 1311—REGISTRATION OF IMPORTERS AND EXPORTERS OF CONTROLLED SUBSTANCES

Sec.

AUTHORITY: 21 U.S.C. 952, 956, 957, 958, unless otherwise noted.

SOURCE: 36 FR 7812, Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

GENERAL INFORMATION

§ 1311.01 Scope of Part 1311.

Procedures governing the registration of importers and exporters of controlled substances pursuant to sections

1007 and 1008 of the Act (21 U.S.C. 957–958) are set forth generally by those sections and specifically by the sections of this part.

§ 1311.02 Definitions.

As used in this part, the following terms shall have the meanings specified:

(a) The term *Act* means the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).

(b) The term *customs territory of the United States* means the several States, the District of Columbia, and Puerto Rico.

(c) The term *export* means, with respect to any article, any taking out or removal of such article from the jurisdiction of the United States (whether or not such taking out or removal constitutes an exportation within the meaning of the customs and related laws of the United States).

(d) The term *exporter* includes every person who exports, or who acts as an export broker for exportation of, controlled substances listed in any schedule.

(e) The term *hearing* means any hearing held pursuant to this part for the granting, denial, revocation or suspension of a registration pursuant to section 1008 of the Act (21 U.S.C. 958).

(f) The term *import* means, with respect to any article, any bringing in or introduction of such article into either the jurisdiction of the United States or the customs territory of the United States, and from the jurisdiction of the United States into the customs territory of the United States (whether or not such bringing in or introduction constitutes an importation within the meaning of the tariff laws of the United States).

(g) The term *importer* includes every person who imports, or who acts as an import broker for importation of, controlled substances listed in any schedule.

(h) The term *jurisdiction of the United States* means the customs territory of the United States, the Virgin Islands, the Canal Zone, Guam, American Samoa, and the Trust Territories of the Pacific Islands.

(i) The terms *register* and *registration* refer only to registration required and permitted by section 1007 of the Act (21 U.S.C. 957).

(j) The term *registrant* means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958).

(k) Any term not defined in this section shall have the definition set forth in section 1001 of the Act (21 U.S.C. 951) or § 1301.02 of this chapter.

[36 FR 7812, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 52 FR 17288, May 7, 1987]

§ 1311.03 Information; special instructions.

Information regarding procedures under these rules and instructions supplementing these rules will be furnished upon request by writing to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005.

[36 FR 7815, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 51 FR 5319, Feb. 13, 1986]

FEES FOR REGISTRATION AND REREGISTRATION

§ 1311.11 Fee amounts.

(a) For each registration or reregistration to import controlled substances, the registrant shall pay an application fee of $438 for an annual registration.

(b) For each registration or reregistration to export controlled substances, the registrant shall pay an application fee of $438 for an annual registration.

[58 FR 15274, Mar. 22, 1993]

§ 1311.12 Time and method of payment; refund.

The time and method of payment of application fees and refunds of application fees shall be as provided in § 1301.12 of this chapter.

[53 FR 4963, Feb. 19, 1988]

REQUIREMENTS OF REGISTRATION

§ 1311.21 Persons required to register.

Every person who imports any controlled substance, or who exports any controlled substance, or who proposes to engage in such importation or exportation, shall obtain annually a registration unless exempted by law or pursuant to §§ 1311.24 through 1311.27. Only persons actually engaged in such activities are required to obtain registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation importing controlled substances is not required to obtain a registration.)

[52 FR 17288, May 7, 1987]

§ 1311.22 Separate registration for independent activities.

(a) Every person who engages in more than one group of independent activities, as described in § 1301.22 of this chapter shall obtain a separate registration for each group of activities as required by that section.

(b) A single registration to engage in any group of independent activities may include one or more controlled substancds listed in the schedules authorized in that group of independent activities. A person registered to conduct research with controlled substances listed in schedule I may conduct research with any substance listed in schedule I for which he has filed and had approved a research protocol.

[36 FR 7812, Apr. 24, 1971, as amended at 36 FR 18734, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1311.23 Separate registrations for separate locations.

(a) A separate registration is required for each principal place of business at one general physical location where controlled substances are imported or exported by a person.

(b) The following locations shall be deemed not to be places where controlled substances are imported or exported:

(1) A warehouse where controlled substances are stored on behalf of a registered person, unless such substances are distributed directly from such warehouse to persons other than the registered person or persons not required to register by virtue of subsection 1007(b)(1)(B) (21 U.S.C. 957(b)(1)(B)); and

(2) An office used by agents of a registrant where sales of controlled substances are solicited, made, or supervised but which neither contains such substances (other than substances for display purposes) nor serves as a distribution point for filling sales orders.

§ 1311.24 Exemption of certain military personnel.

The requirement of registration is waived for any official or agency of the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, or Public Health Service who or which is authorized to import or export controlled substances in the course of his official duties.

[36 FR 7812, Apr. 24, 1971, as amended at 36 FR 18734, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1311.25 Exemption of law enforcement officials.

The requirement of registration is waived for any officer or employee of the Administration, any officer of the U.S. Customs Service, any officer or employee of the U.S. Food and Drug Administration, and any other Federal officer who is lawfully engaged in the enforcement of any Federal law relating to controlled substances, drugs or customs, and is duly authorized to possess, import or export controlled substances in the course of his official duties.

§ 1311.26 Exemption for ocean vessels, commercial aircraft, and certain other entities.

Owners or operators of vessels, aircraft, or other entities described in § 1301.28 of this chapter or in Article 32 of the Single Convention on Narcotic Drugs, 1961, or in Article 14 of the Convention on Psychotropic Substances, 1971, shall not be deemed to import or export any controlled substances purchased and stored in accordance with that section or applicable article.

[52 FR 17288, May 7, 1987]

§1311.27 Exemptions for personal medical use.

Any individual who has in his possession a controlled substance listed in schedules II, III, IV, or V, which he has lawfully obtained for his personal medical use, or for administration to an animal accompanying him, may enter or depart the United States with such substance notwithstanding sections 1002–1005 of the Act (21 U.S.C. 952–955), providing the following conditions are met:

(a) The controlled substance is in the original container in which it was dispensed to the individual; and

(b) The individual makes a declaration to an appropriate official of the U.S. Customs Service stating:

(1) That the controlled substance is possessed for his personal use, or for an animal accompanying him; and

(2) The trade or chemical name and the symbol designating the schedule of the controlled substance if it appears on the container label, or, if such name does not appear on the label, the name and address of the pharmacy or practitioner who dispensed the substance and the prescription number, if any.

[36 FR 7812, Apr. 24, 1971, as amended at 36 FR 13387, July 21, 1971; 36 FR 18734, Sept. 21, 1971. Redesignated at 37 FR 15922, Aug. 8, 1972, and at 38 FR 26609, Sept. 24, 1973]

APPLICATIONS FOR REGISTRATION

§1311.31 Time for application for registration; expiration date.

(a) Any person who is required to be registered and who is not so registered may apply for registration at any time. No person required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a Certificate of Reghstration is issued by the Administrator of such person.

(b) Any person who is registered may apply to be reregistered not more than 60 days before the expiration date of his registration.

(c) At the time any person is first registered, he will be assigned to one of 12 groups in the same manner and with the same effect as provided in §1301.31 of this chapter.

[36 FR 7812, Apr. 24, 1971, as amended at 36 FR 18734, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

§1311.32 Application forms; contents; signature.

(a) Any person who is required to be registered to import or export controlled substances, and who is not so registered, shall apply on DEA Form 225.

(b) Any person who is registered to import or export controlled substances, shall apply for reregistration on DEA Form 225a.

(c) DEA Form 225 may be obtained at any regional office of the Administration or by writing to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005. DEA Form 225a will be mailed to each registered importer and exporter approximately 60 days before the expiration date of his registration; if any registered person does not receive such forms within 45 days before the expiration date of his registration, he must promptly give notice of such fact and request such forms by writing to the Registration Branch of the Administration at the foregoing address.

(d) Each application for registration to import or export controlled substances shall include the Administration Controlled Substances Code Number, as set forth in part 1308 of this chapter, for each controlled substance whose importation or exportation is to be authorized by such registration.

(e) Registration as an importer or exporter shall not entitle a registrant to import or export any controlled substance not specified in such registration.

(f) Each application shall include all information called for in the form, unless the item is not applicable, in which case this fact shall be indicated.

(g) Each application, attachment, or other document filed as part of an application, shall be signed by the applicant, if an individual; by a partner of the applicant, if a partnership; or by an officer of the applicant, if a corporation, association, trust or other entity.

An applicant may authorize one or more individuals, who would not otherwise be authorized to do so, to filing applications for the applicant by filing with the Registration Unit of the Administration a power of attorney for each such individual. The power of attorney shall be signed by a person who is authorized to sign applications under this paragraph and shall contain the signature of the individual being authorized to sign applications. The power of attorney shall be valid until revoked by the applicant.

[36 FR 7812, Apr. 24, 1971, as amended at 36 FR 18734, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 51 FR 5319 and 5320, Feb. 13, 1986; 52 FR 17288, May 7, 1987; 53 FR 4963, Feb. 19, 1988]

§ 1311.33 Filing of application; acceptance for filing; additional information; amendments to and withdrawals of applications.

Applications for registration to import or export controlled substances shall be filed, accepted for filing, supplemented, amended and withdrawn as provided in §§ 1301.34–1301.37 of this chapter.

ACTION ON APPLICATIONS FOR REGISTRATION: REVOCATION OR SUSPENSION OF REGISTRATION

§ 1311.41 Administrative review generally.

The Administrator may inspect, or cause to be inspected, the establishment of an applicant or registrant, pursuant to subpart A of part 1316 of this chapter. The Administrator shall review the application for registration and other information gathered by the Administrator regarding an applicant in order to determine whether the applicable standards of section 1008 of the Act (21 U.S.C. 958) have been met by the applicant.

§ 1311.42 Application for importation of Schedule I and II substances.

(a) In the case of an application for registration or reregistration to import a controlled substance lhsted in Schedule I or II, under the authority of section 1002(a)(2)(B) of the Act (21 U.S.C. 952(a)(2)(B)), the Administrator shall, upon the filing of such application, publish in the FEDERAL REGISTER a notice naming the applicant and stating that such applicant has applied to be registered as an importer of a Schedule I or II controlled substance, which substance shall be identified. A copy of said notice shall be mailed simultaneously to each person registered as a bulk manufacturer of that controlled substance and to any other applicant therefor. Any such person may, within 30 days from the date of publication of the notice in the FEDERAL REGISTER, file written comments on or objections to the issuance of the proposed registration, and may, at the same time, file a written request for a hearing on the application pursuant to § 1301.54. If a hearing is requested, the Administrator shall hold a hearing on the application in accordance with § 1301.54. Notice of the hearing shall be published in the FEDERAL REGISTER, and shall be mailed simultaneously to the applicant and to all persons to whom notice of the application was mailed. Any such person may participate in the hearing by filing a notice of appearance in accordance with § 1301.54 of this chapter. Notice of the hearing shall contain a summary of all comments and objections filed regarding the application and shall state the time and place for the hearing, which shall not be less than 30 days after the date of publication of such notice in the FEDERAL REGISTER. A hearing pursuant to this section may be consolidated with a hearing held pursuant to §§ 1311.43 or 1311.44 of this part.

(b) The Administrator shall register an applicant to import a controlled substance listed in Schedule I or II if he determines that such registration is consistent with the public interest and with U.S. obligations under international treaties, conventions, or protocols in effect on May 1, 1971. In determining the public interest, the following factors shall be considered:

(1) Maintenance of effective controls against diversion of particular controlled substances and any controlled substance in Schedule I or II compounded therefrom into other than legitimate medical, scientific research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce

an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) Compliance with applicable State and local law;

(3) Promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) Prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) Past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion;

(6) That the applicant will be permitted to import only:

(i) Such amounts of crude opium, poppy straw, concentrate of poppy straw, and coca leaves as the Administrator finds to be necessary to provide for medical, scientific, or other legitimate purposes; or

(ii) Such amounts of any controlled substances listed in Schedule I or II as the Administrator shall find to be necessary to provide for the medical, scientific, or other legitimate needs of the United States during an emergency in which domestic supplies of such substances are found by the Administrator to be inadequate; or

(iii) Such amounts of any controlled substance listed in Schedule I or II as the Administrator shall find to be necessary to provide for the medical, scientific, or other legitimate needs of the United States in any case in which the Administrator finds that competition among domestic manufacturers of the controlled substance is inadequate and will not be rendered adequate by the registration of additional manufacturers under section 303 of the Act (21 U.S.C. 823); or

(iv) Such limited quantities of any controlled substance listed in Schedule I or II as the Administrator shall find to be necessary for scientific, analytical or research uses; and

(7) Such other factors as may be relevant to and consistent with the public health and safety.

(c) In determining whether the applicant can and will maintain effective controls against diversion within the meaning of paragraph (b), the Administrator shall consider among other factors:

(1) Compliance with the security requirements set forth in §§ 1301.71–1301.76 of this chapter; and

(2) Employment of security procedures to guard against in-transit losses within and without of the jurisdiction of the United States.

(d) In determining whether competition among the domestic manufacturers of a controlled substance is adequate within the meaning of paragraphs (b)(1) and (6)(iii) of this section, as well as section 1002(a)(2)(B) of the Act (21 U.S.C. 952(a)(2)(B)), the Administrator shall consider:

(1) The extent of price rigidity in the light of changes in (i) raw materials and other costs and (ii) conditions of supply and demand;

(2) The extent of service and quality competition among the domestic manufacturers for shares of the domestic market including (i) shifts in market shares and (ii) shifts in individual customers among domestic manufacturers;

(3) The existence of substantial differentials between (i) domestic prices and (ii) the higher of prices generally prevailing in foreign markets or the prices at which the applicant for registration to import is committed to undertake to provide such products in the domestic market in conformity with the Act. In determining the existence of substantial differentials hereunder, appropriate consideration should be given to any additional costs imposed on domestic manufacturers by the requirements of the Act and such other cost-related and other factors as the Administrator may deem relevant. In no event shall an importer's offering prices in the United States be considered if they are lower than those prevailing in the foreign market or markets from which the importer is obtaining his supply;

(4) The existence of competitive restraints imposed upon domestic manufacturers by governmental regulations; and

(5) Such other factors as may be relevant to the determinations required under this paragraph.

(e) In considering the scope of the domestic market, consideration shall be given to substitute products which are reasonably interchangeable in terms of price, quality and use.

(f) The fact that the number of existing manufacturers is small shall not demonstrate, in and of itself, that adequate competition among them does not exist.

[36 FR 7812, Apr. 24, 1971, as amended at 36 FR 18734, Sept. 21, 1971; 37 FR 15922, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 52 FR 17288, May 7, 1987]

§ 1311.43 Certificate of registration; denial of registration.

(a) The Administrator shall issue a Certificate of Registration (DEA Form 223) to an applicant if the issuance of registration or reregistration is required under the applicable provisions of section 1008 of the Act (21 U.S.C. 958). In the event the issuance of registration or reregistration is not required, the Administrator shall deny the application. Before denying any application, the Administrator shall issue an order to show cause pursuant to § 1311.47 and, if requested by the applicant, shall hold a hearing on the application pursuant to § 1311.51.

(b) The Certificate of Registration (DEA Form 223) shall contain the information, and shall be maintained in the manner prescribed in § 1301.44(b) of this chapter.

[36 FR 7812, Apr. 24, 1971, as amended at 37 FR 15922, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 53 FR 4963, Feb. 19, 1988]

§ 1311.44 Surpension or revocation of registration.

(a) The Administrator may suspend any registration pursuant to section 1008(d) of the Act (21 U.S.C. 958(d)) for any period of time.

(b) The Administrator may revoje or suspend a registration issued under section 1008(d) of the Act (21 U.S.C. 958(d)) if he determines that such registration is inconsistent with the public interest as defined in that section or with the United States obligations under international treaties, conventions, or protocols in effect on October 12, 1984.

(c) The Administrator may revoke or suspend a registration issued under section 1008(c) of the Act (21 U.S.C. 958(c)) if he determines that such registration is inconsistent with the public interest as defined in that section or with the United States obligations under international treaties, conventions, or protocols in effect on October 12, 1984.

(d) The Administrator may limit the revocation or suspension of a registration to the particular controlled substance, or substances, with respect to which grounds for revocation or suspension exist.

(e) Before revoking or suspending any registration, the Administrator shall issue an order to show cause pursuant to § 1311.47, and if requested by the registrant, shall hold a hearing pursuant to § 1311.51. Notwithstanding the requirements of this section, however, the Administrator may suspend any registration pending a final order pursuant to § 1311.45.

(f) Upon service of the order of the Administrator suspending or revoking registration, the registrant shall immediately deliver his Certificate of Registration and any order forms and import or export permits in his possession to the nearest office of the Administrator. The suspension or revocation of a registration shall suspend or revoke any import or export permits issued pursuant to part 1312 of this chapter. Also, upon service of the order of the Administrator revoking or suspending registration, the registrant shall, as instructed by the Administrator:

(1) Deliver all controlled substances in his possession to the nearest office of the Administration pursuant to section 1008(d)(6) of the Act (21 U.S.C. 958(d)(6)); or

(2) Deliver all controlled substances in his possession to authorized agents of the Administration who will either remove the substances or place them under seal as described in section as described in section 1008(d)(6) of the Act (21 U.S.C. 1008(d)(6)).

(g) In the event that revocation or suspension is limited to a particular controlled substance or substances, the registrant shall be given a new Certificate of Registration for all substances

not affected by such revocation or suspension. The registrant shall deliver the old Certificate of Registration and, if appropriate, any order forms and import or export permits in his possession to the nearest office of the Administrator. Also, upon service of the order of the Administrator revoking or suspending registration, the registrant shall, as instructed by the Administrator:

(1) Deliver to the nearest office of the Administration, pursuant to section 1008(d)(6) of the Act (21 U.S.C. 958(d)(6)), all of the particular controlled substance or substances affected by the revocation or suspension which are in his possession; or

(2) Deliver all of such substances to authorized agents of the Administration who will either remove the substances or place them under seal as described in section 1008(d)(6) of the Act (21 U.S.C. 958(d)(6)).

[36 FR 7812, Apr. 24, 1971, as amended at 36 FR 13387, July 21, 1971; 37 FR 15922, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 52 FR 17288, May 7, 1987]

§ 1311.45 Suspension of registration pending final order.

(a) The Administrator may suspend any registration simultaneously with or at any time subsequent to the service upon the registrant of an order to show cause why such registration should not be revoked or suspended, in any case where he finds that there is an imminent danger to the public health or safety. If the Administrator so suspends, he shall serve with the order to show cause pursuant to § 1311.47 an order of immediate suspension which shall contain a statement of his findings regarding the danger to public health or safety.

(b) Upon receipt of the order of immediate suspension, the registrant shall promptly return his Certificate of Registration and any other forms and import or export permits in his possession to the nearest office of the Administrator. The suspension of any registration under this section shall suspend any import and export permits issued pursuant to part 1312 of this chapter.

(c) Any suspension shall continue in effect until the conclusion of all proceedings upon revocation or suspension, including any judicial review thereof, unless sooner withdrawn by the Administrator or dissolved by a court of competent jurisdiction. Any registrant whose registration is suspended under this section may request a hearing on the revocation or suspension of his registration at a time earlier than specified in the order to show cause pursuant to § 1311.47 which request shall be granted by the Administrator, who shall fix a date for such hearing as early as reasonably possible.

§ 1311.46 Extension of registration pending final order.

An applicant for reregistration (who is doing business under a registration previously granted and not revoked or suspended) may have the existing registration extended and continue in effect until the date on which the Administrator issues his order on the application for reregistration as provided in § 1301.47 of this chapter.

§ 1311.47 Order to show cause.

(a) If, upon examination of the application for registration from any applicant and other information gathered by the Administration regarding the applicant, the Administrator is unable to make the determinations required by the applicable provisions of sections 303 and 1008(d) of the Act (21 U.S.C. 823 and 958(d)) to register the applicant, the Administrator shall serve upon the applicant an order to show cause why the application for registration should not be denied, as provided in § 1301.48 of this chapter.

(b) If, upon information gathered by the Administration regarding any registrant, the Administrator determines that the registration of such registrant is subject to suspension or revocation pursuant to section 1008(d) of the Act (21 U.S.C. 958(d)), the Administrator shall serve upon the registrant an order to show cause why the registration should not be revoked or suspended, as provided in § 1301.48 of this chapter.

[52 FR 17289, May 7, 1987]

HEARINGS

§ 1311.51 Hearings generally.

(a) In any case where the Administrator shall hold a hearing on any registration or application thereof, the procedures for such hearing shall be governed generally by the adjudication procedures set forth in the Administrative Procedure Act (5 U.S.C. 551–559) and specifically by section 1008 of the Act (21 U.S.C. 958), by §§ 1311.52–1311.53, by the procedures for hearings pursuant to sections 303 and 304 of the Act (21 U.S.C. 823–824) set forth in §§ 1301.51–1301.57 of this chapter, and by the procedures for administrative hearings under the Act set forth in §§ 1316.41–1316.67 of this chapter.

(b) Any hearing under this part shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under the Act or any other law of the United States.

[36 FR 7812, Apr. 24, 1971, as amended at 36 FR 13387, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1311.52 Hearings on application for importation of Schedule I and II substances.

A hearing on an application for registration to import a basic class of any controlled substance listed in Schedule I or II required by § 1311.42 shall be held under the same procedures prescribed in §§ 1301.51–1301.57 of this chapter for a hearing on an application for registration to manufacture in bulk a basic class of any controlled substance.

[36 FR 7812, Apr. 24, 1971, as amended at 36 FR 13387, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1311.53 Burden of proof.

(a) At any hearing on the granting or denial of an application to be registered to import or export any controlled substance listed in Schedule I or II, the applicant shall have the burden of proving that the requirements for such registration pursuant to sections 1008 (a) and (d) of the Act (21 U.S.C. 958 (a) and (d)) are satisfied. Any other person participating in the hearing pursuant to § 1311.42 shall have the burden of proving any propositions of fact or law asserted by him in the hearings.

(b) At any other hearing for the denial of an application for registration, the Administration shall have the burden of proving that the requirements for such registration pursuant to sections 1008 (c) and (d) of the Act (21 U.S.C. 958 (c) and (d)) are not satisfied.

(c) At any hearing for the revocation or suspension of a registration, the Administration shall have the burden of proving that the requirements for such revocation or suspension pursuant to section 1008(d) of the Act (21 U.S.C. 958(d)) are satisfied.

[52 FR 17289, May 7, 1987]

MODIFICATION, TRANSFER, AND TERMINATION OF REGISTRATION

§ 1311.61 Modification in registration.

Any registrant may apply to modify his registration to authorize the handling of additional controlled substances or to change his name or address, by submitting a letter of request to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005. The letter shall contain the registrant's name, address, and registratinn number as printed on the Certificate of Registration, and the substances (including the schedule and the Administration Controlled Substances Code Number, as set forth in part 1308 of this chapter, for those substances) to be added to his registration or the new name and address, and shall be signed in accordance with § 1311.32(f). No fee is required for the modification. The request for modification shall be handled in the same manner as an application for registration. If the modification in registration is approved, the Administrator shall issue a new Certificate of Registration (DEA Form 223) to the registrant, who shall maintain it with the old Certificate of Registration until expiration.

[52 FR 17289, May 7, 1987]

§ 1311.62 Termination of registration.

The registration of any person shall terminate if and when such person dies, ceases legal existence or discontinues business or professional practice. Any registrant who ceases legal existence

or discontinues business or professional practice shall notify the Administrator promptly of such fact.

[37 FR 15923, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1311.63 Transfer of registration.

No registration or any authority conferred thereby shall be assigned or otherwise transferred except upon such conditions as the Administrator may specifically designate and then only pursuant to his written consent.

[36 FR 18735, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

PART 1312—IMPORTATION AND EXPORTATION OF CONTROLLED SUBSTANCES

Sec.

AUTHORITY: 21 U.S.C. 952, 953, 954, 957, 958.

SOURCE: 36 FR 7815, Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

§ 1312.01 Scope of part 1312.

Procedures governing the importation, exportation, transshipment and intransit shipment of controlled substances pursuant to section 1002, 1003, and 1004 of the Act (21 U.S.C. 952, 953, and 954) are governed generally by those sections and specifically by the sections of this part.

§ 1312.02 Definitions.

As used in this part, the following terms shall have the meanings specified:

(a) The term *Act* means the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).

(b) Any term not defined in this section shall have the definition set forth in sections 1001 and 102 of the Act (21 U.S.C. 951 and 802) and § 1311.02 of this chapter.

[36 FR 7815, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 51 FR 5320, Feb. 13, 1986]

IMPORTATION OF CONTROLLED SUBSTANCES

§ 1312.11 Requirement of authorization to import.

(a) No person shall import or cause to be imported any controlled substance listed in Schedule I or II or any narcotic controlled substance listed in Schedule III, IV or V or any non-narcotic controlled substance in Schedule III which the Administrator has specifically designated by regulation in